The Result of the Guide-CRT Trial

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SPECT Guided Left Ventricular Lead Placement for Improved CRT Efficacy (Guide-CRT)

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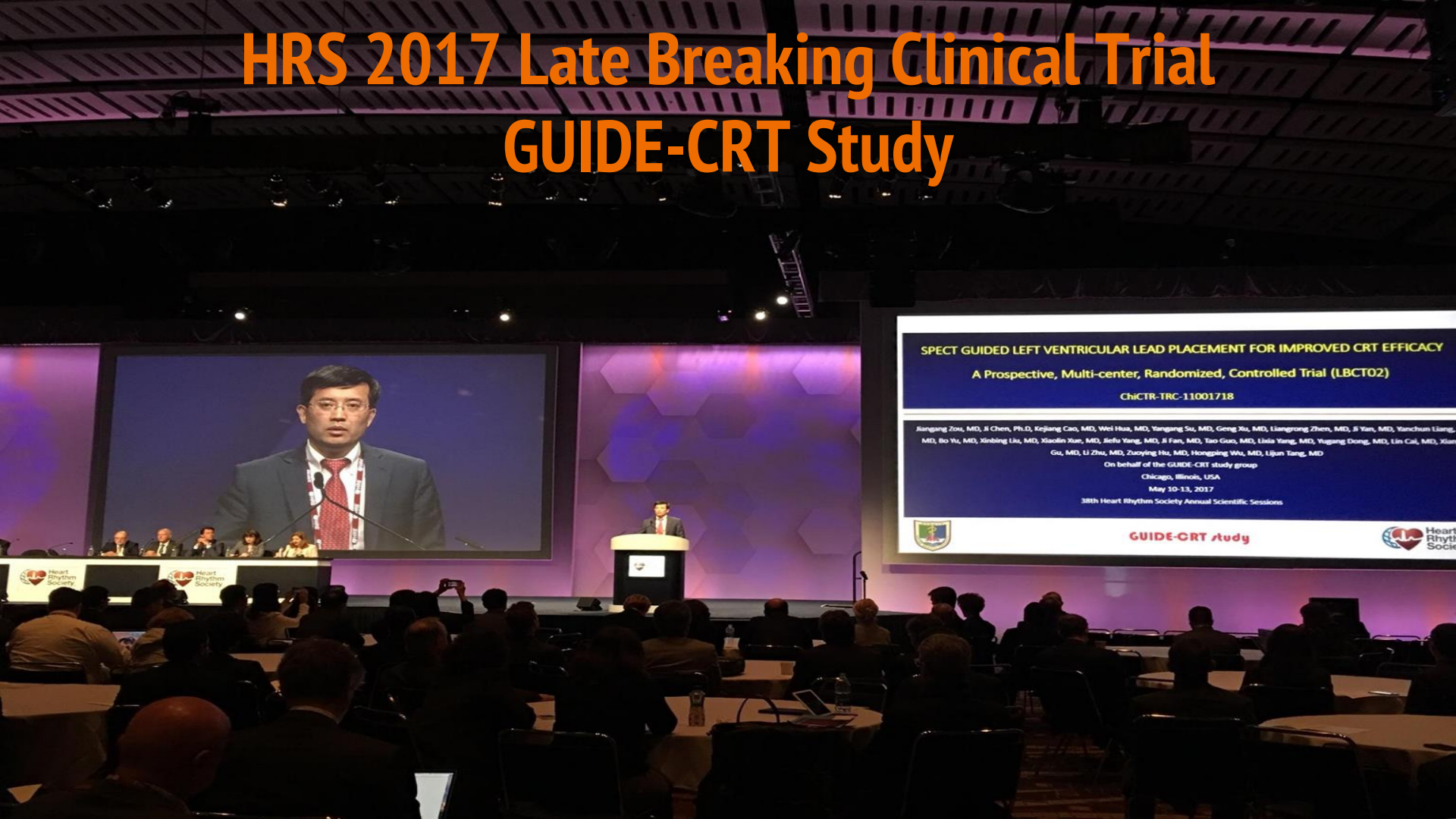
Sponsor: Nanjing medical university and Medtronic shanghai Lit. co

Guide-CRT Study Investigator Group

HRS 2017 Late Breaking Clinical Trial
GUIDE-CRT Study



Background

- CRT is an effective treatment for chronic heart failure. The standard criteria [1] for patients to receive CRT include:
  - NYHA class II-IV
  - LVEF <= 35%
  - QRS >= 120 ms
- Based on the standard criteria, 30-40% of the patients do not show CRT response in LV reverse remodeling and clinical outcome [2-5]
- LV lead position is the major factor related to CRT response [6]

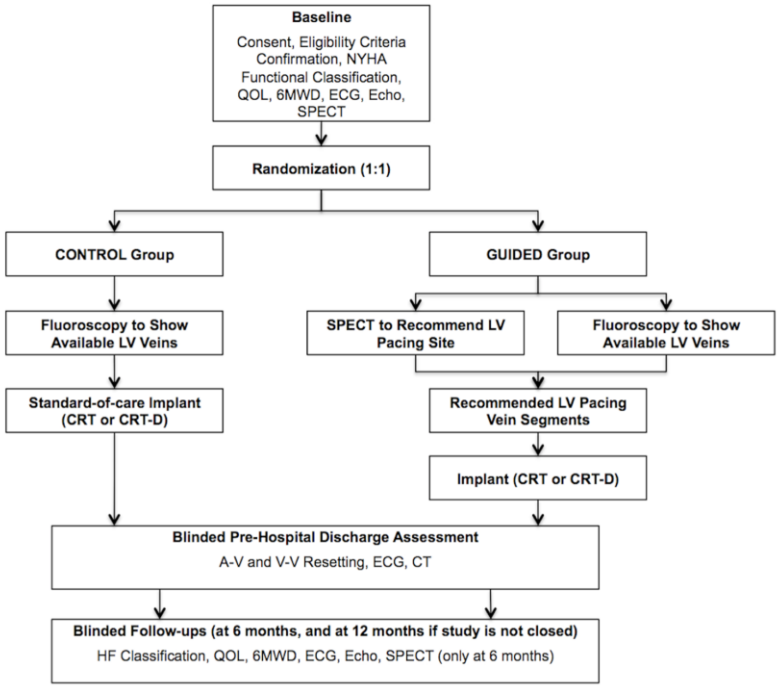
Background

- Phase analysis is an automated technique to assess LV mechanical dyssynchrony from SPECT MPI [7]
- Phase analysis of SPECT MPI has been shown to identify the site of latest activation as the optimal LV lead position for CRT [8]
- Due to its automation and simplicity, SPECT MPI has been utilized successfully as the one-stop shop for CRT response predictors, such as LV dyssynchrony, site of latest activation, and scar burden [9]

Objective

- Validate the usefulness of SPECT MPI to guide LV lead placement for increasing the benefit to CRT in currently indicated patients

Study Design



- Prospective, multicenter, randomized, controlled trial
- 19 centers in China
- Core labs
  - Echo (Nanjing Medical University)
  - CT (Nanjing Medical University)
  - SPECT (Emory University)
- Primary endpoint is LVESV change from baseline to 6-month follow-up
- Secondary endpoints include LVEDV change, LVEF change, and CRT response

Enrollment Criteria

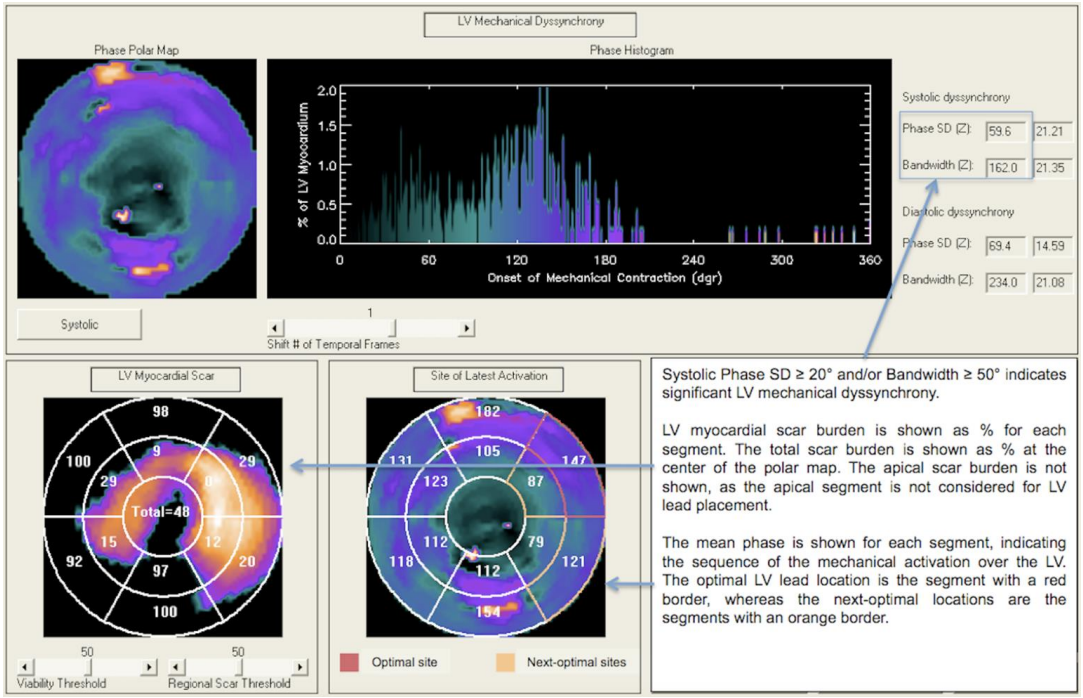
Inclusion Criteria:

- Patient has signed and dated study informed consent.
- Patient is able to receive pectoral implant
- Patient is indicated for either Medtronic CRT or CRT-D system
- Patient has moderate to severe HF (NYHA Class II, III or IV)
- Patient has LVEF <=35%
- Patient has QRS duration >=120 ms
- Patient is in sinus rhythm

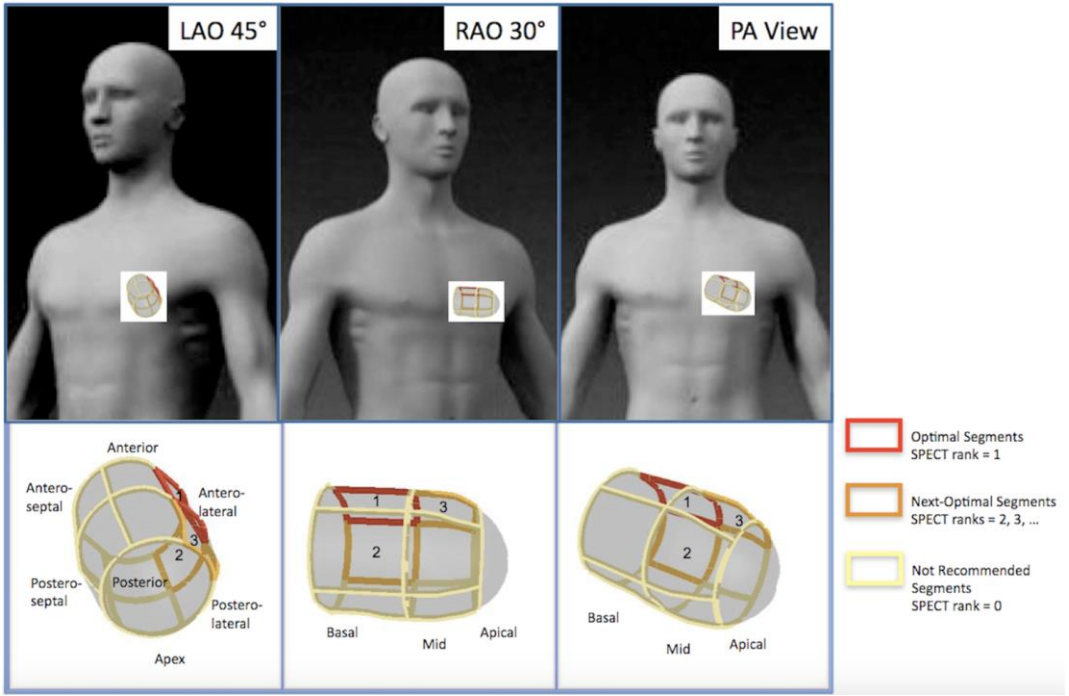
Exclusion Criteria:

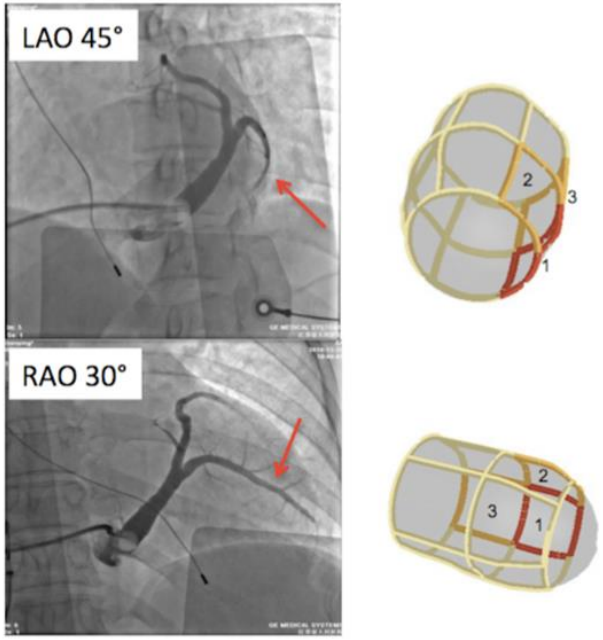
- Patient is under a minimum age requirement
- Patient has mechanical right heart valve
- Patient has experienced unstable angina, acute MI, CABG or PTCA within the past 3 months
- Patient is on continuous or intermittent intravenous inotropic drug therapy
- Patient known to have chronic permanent atrial arrhythmias
- Patient is enrolled in any concurrent study that would confound the results of this study
- Patient has a life expectancy <12 months
- Women who are pregnant, or with childbearing potential without birth control
- Patient with CRT device implanted previously
- Patient has had a heart transplant

Phase Analysis of SPECT MPI

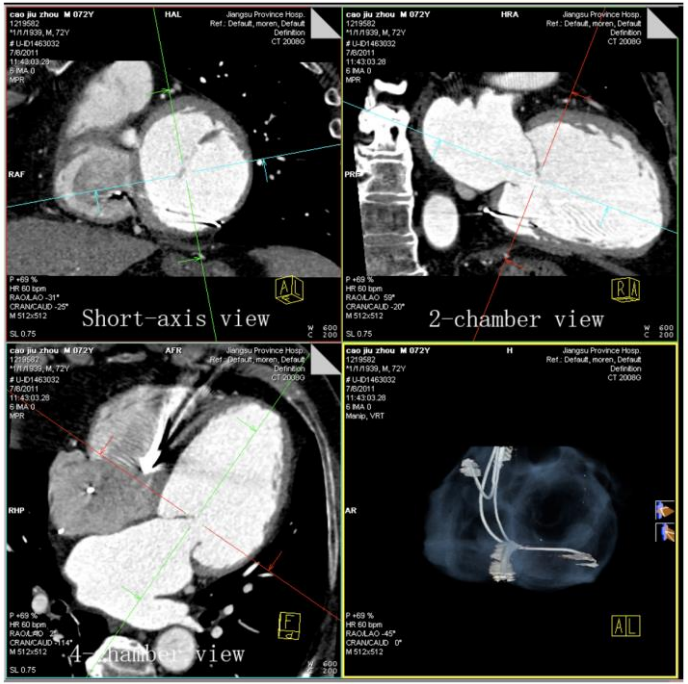


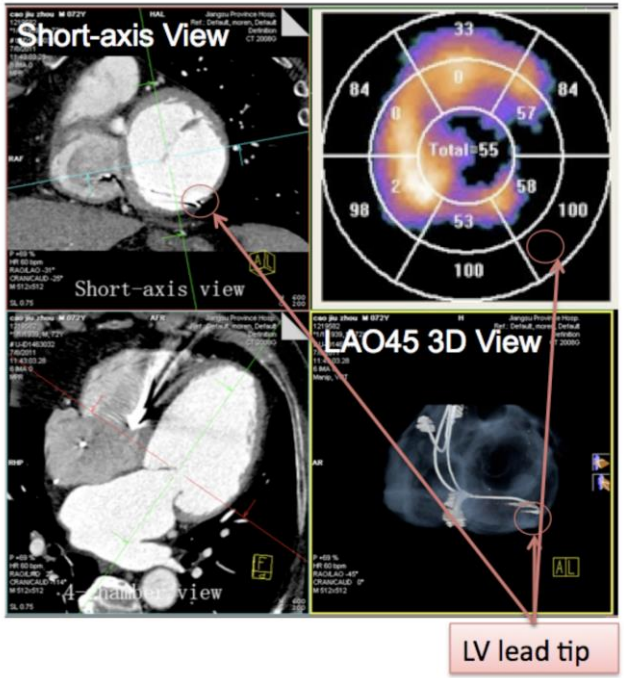
SPECT-Guided Implantation



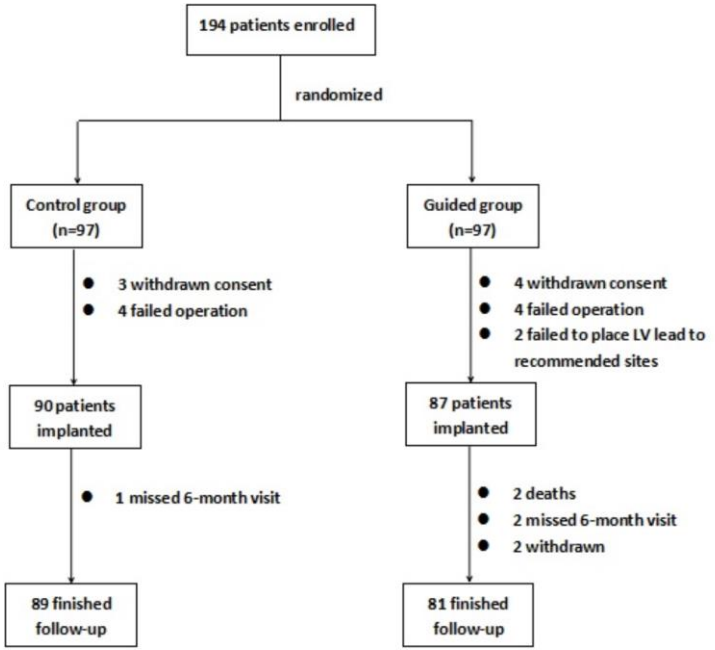


Post-implant CT to Locate LV Leads





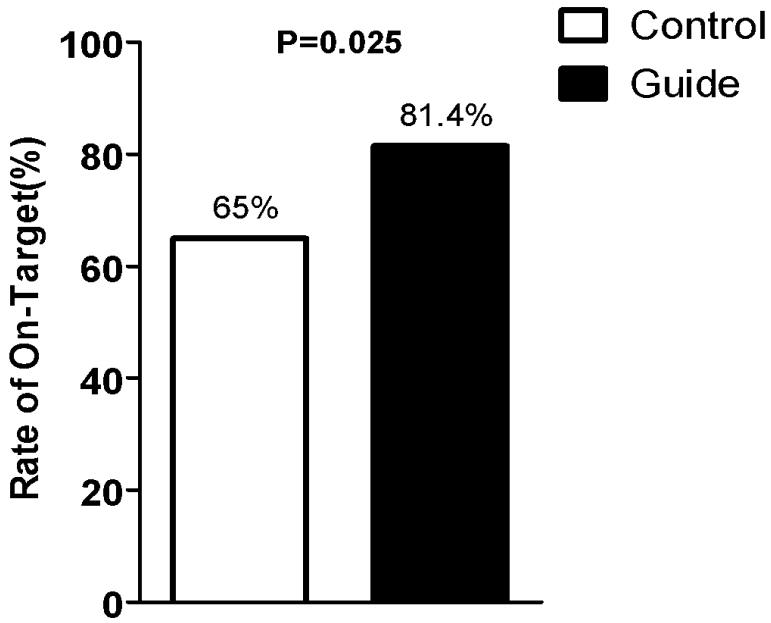
Results: Enrollment and Baseline Characteristics



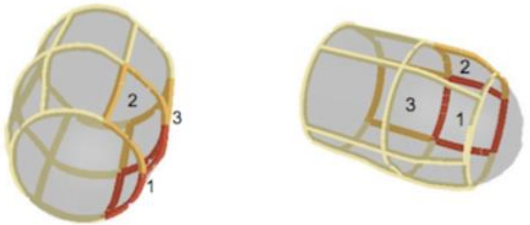
Baseline Characteristics

	Control group (n=90)	Guided group (n=87)	P value
Age	62.7 ± 11.2	62.5 ± 11.5	0.29
Gender Male	65 (72.2)	59 (67.8)	0.62
Etiology ICM NICM	15 (16.7) 75 (83.3)	16 (18.3) 71 (81.6)	0.76
NYHA functional class II/III/IV	18/55/17	18/52/17	0.99
LBBB	83 (92.2)	78 (89.7)	0.79
QRS duration, ms	161.2 ± 24.2	163.6 ± 23.6	0.52
LVEDV, ml	258.6 ± 91.3	252.5 ± 91.5	0.51
LVESV, ml	189.5 ± 76.8	187.3 ± 77.9	0.68
LVEF, %	27.3 ± 6.2	26.7 ± 6.2	0.50
Moderate/severe MR	27/19	17/18	0.59
SPECT MPI			
PSD	54.6 ± 19.5	52.9 ± 19.3	0.57
PHB	184.5 ± 74.8	180.6 ± 74.5	0.73
Scar burden	30.8 ± 13.2	27.8 ± 14.5	0.15
6-MWT	315.7 ± 102.8	301.9 ± 109.5	0.39
QOL score	42.2 ± 19.7	40.26 ± 18.8	0.51

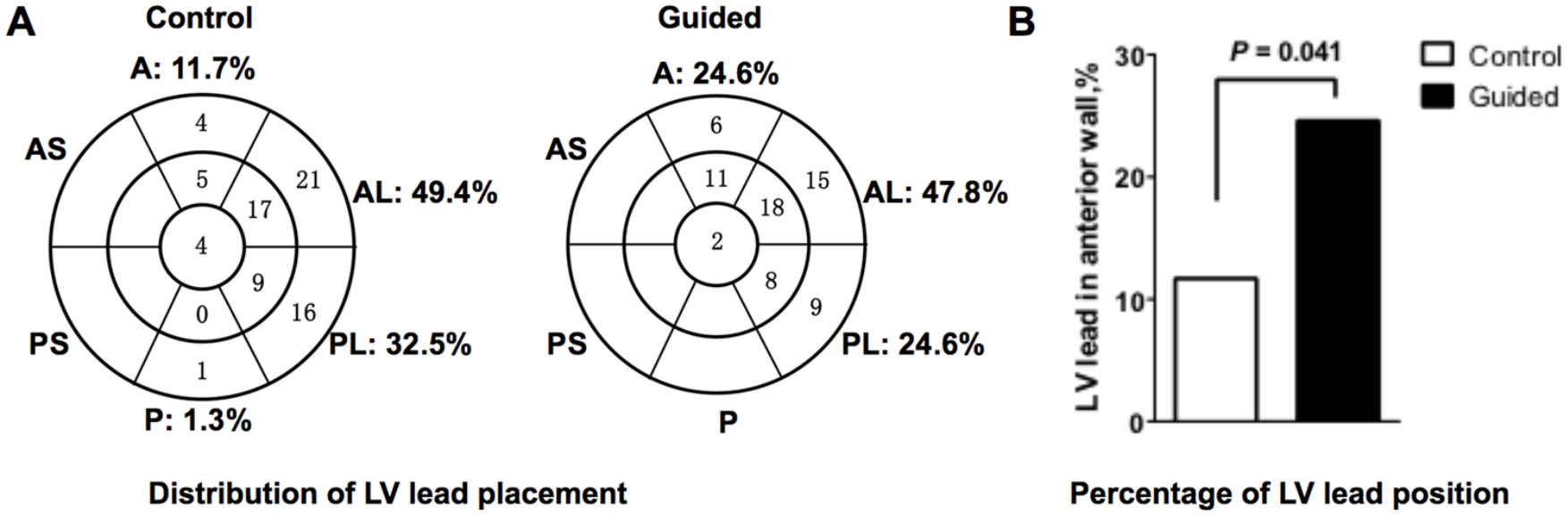
Results: LV Lead Placement



- SPECT-guided implantation resulted in a significantly higher on-target rate than the standard-of-care implantation
- On-target implantation is defined as the LV leads placed in the optimal or suboptimal regions



Results: LV Lead Placement



Distribution of LV lead placement

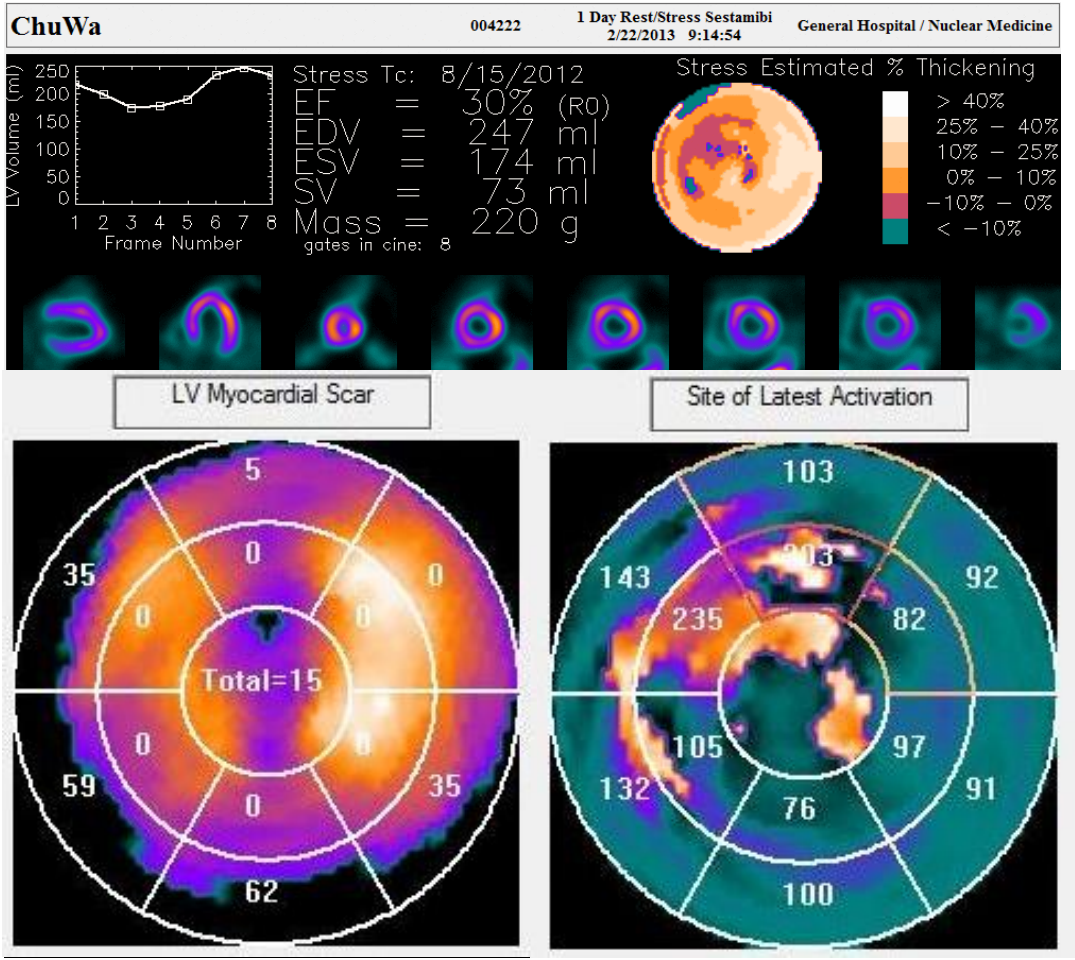
Percentage of LV lead position

A significant portion of the patients in the guided group received anterior LV lead placement, different from the conventional lateral/posterolateral positions

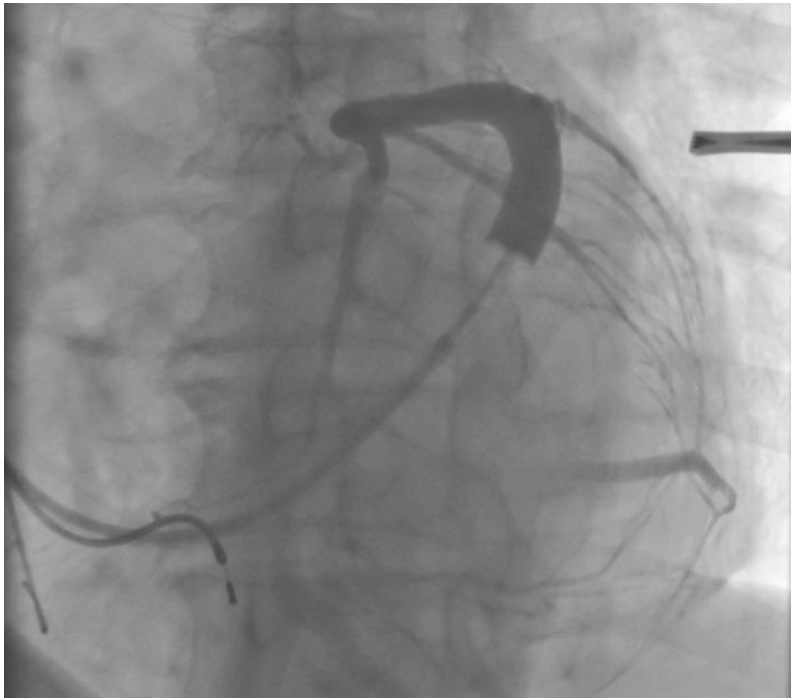
Patient Example 1

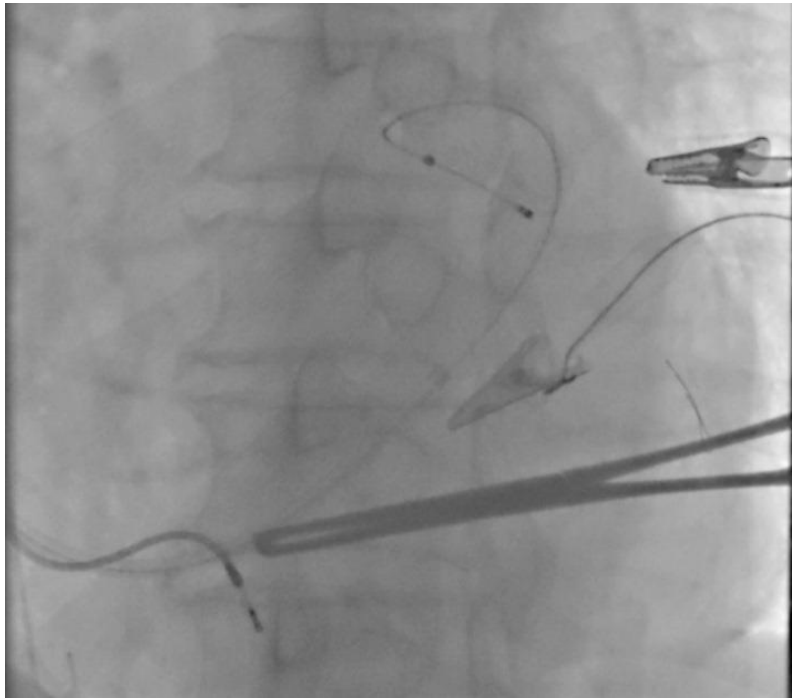
- Age 65, male
- Nonischemic cardiomyopathy
- Heart failure class III
- LVEF = 30%
- QRS duration = 167 ms

Anterior LV lead targeted to the site of latest activation

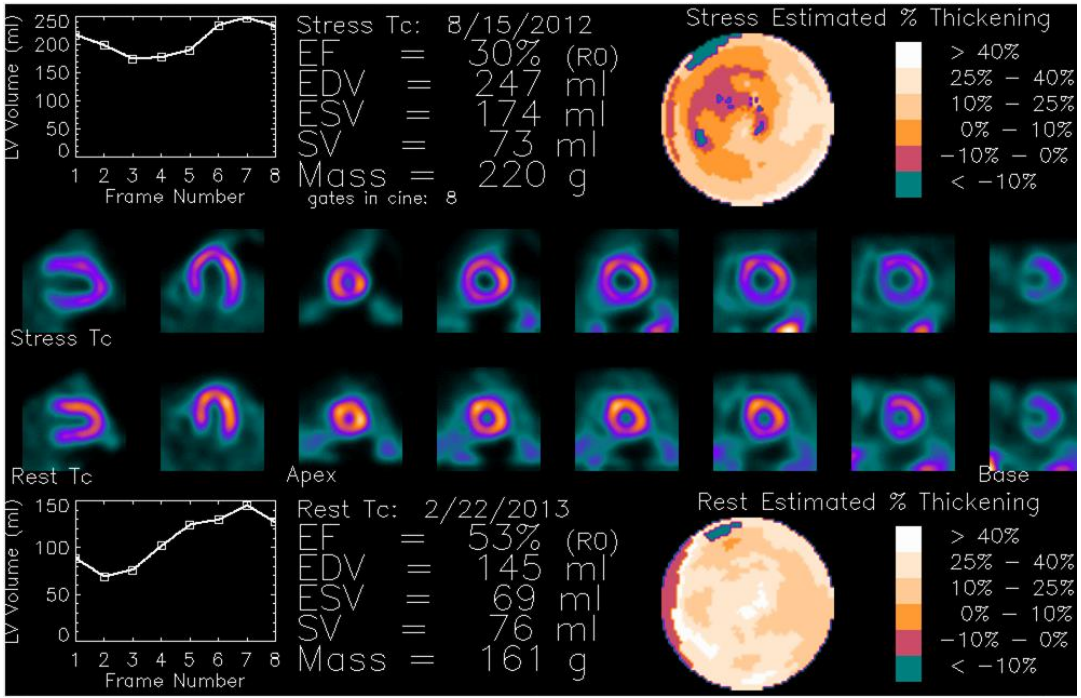


Patient Example 1: Pacing Latest Activation Site





Patient Example 1: Outcome



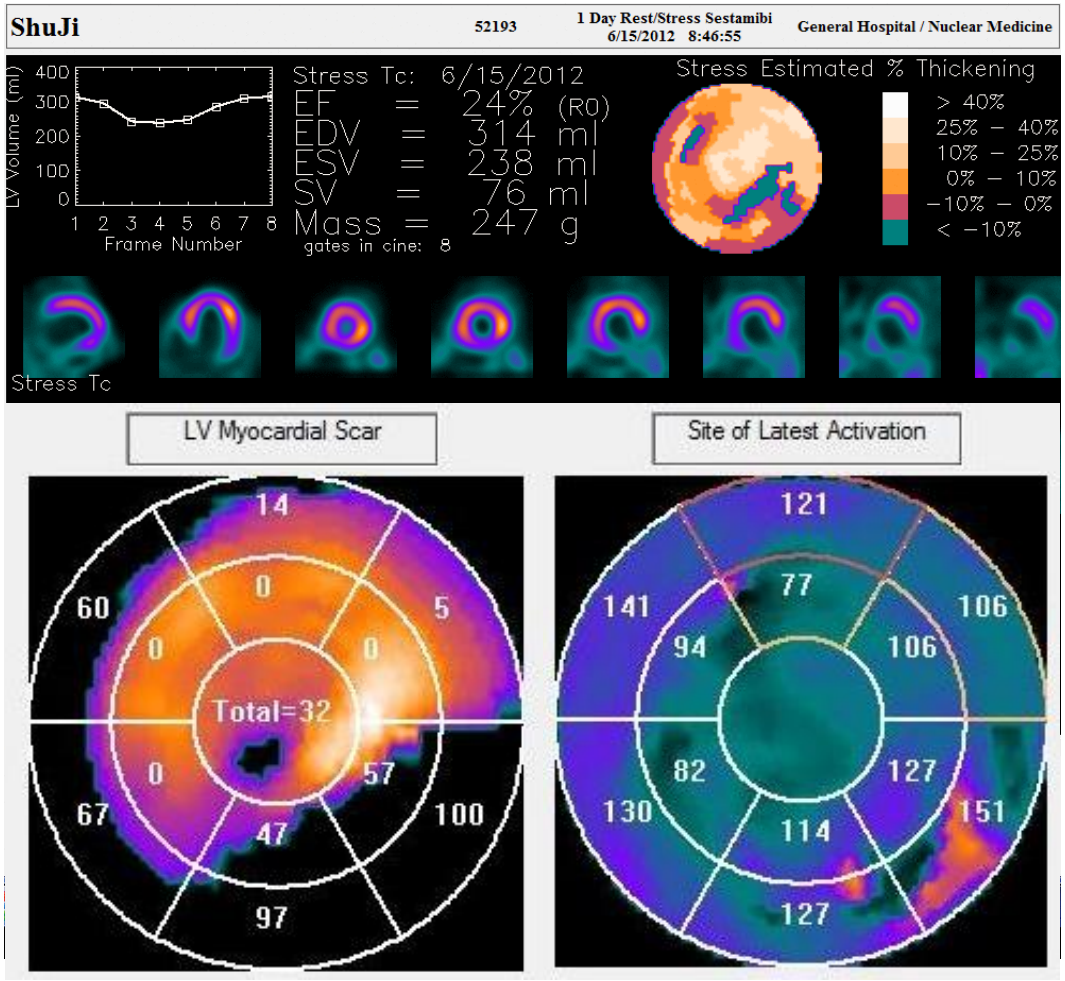
Baseline

Follow-up

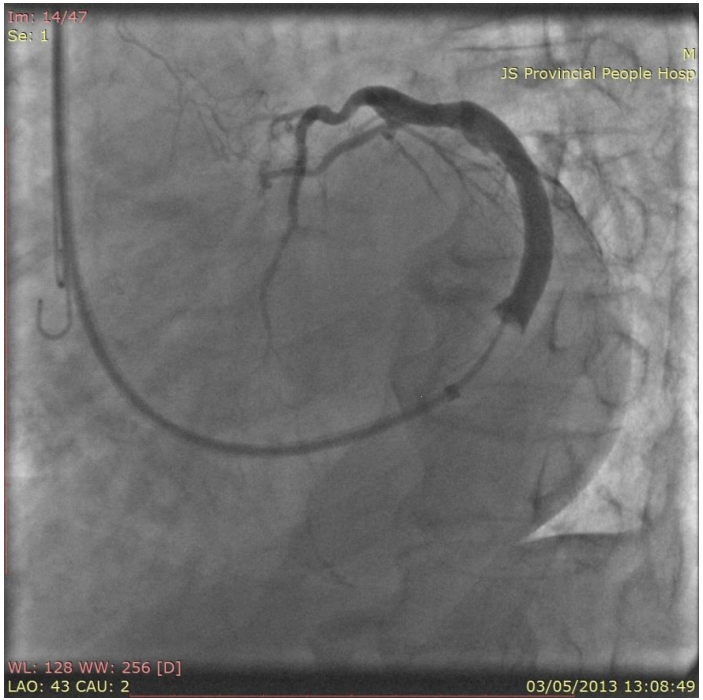
Patient Example 2

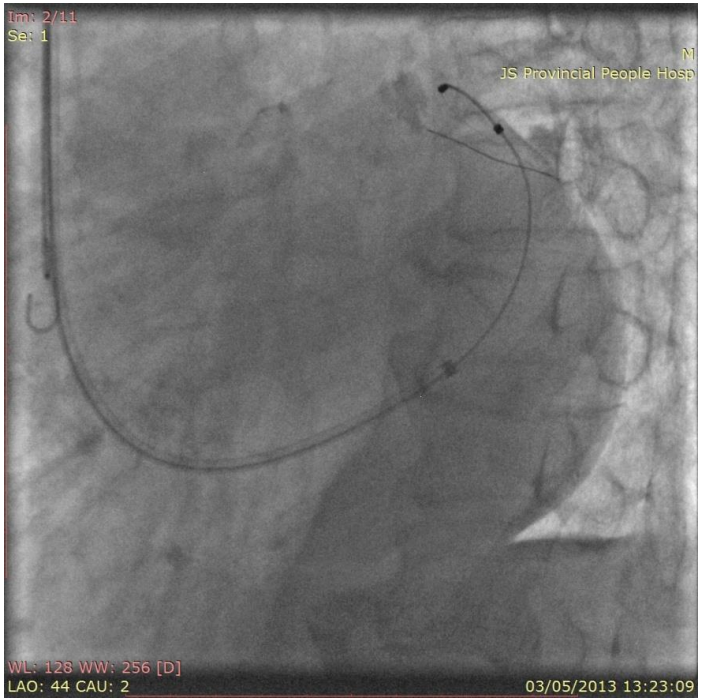
- Age 72, female
- Ischemic cardiomyopathy
- Heart failure class III
- LVEF = 24%
- QRS duration = 173 ms

Anterior LV lead placed away from posterior scar

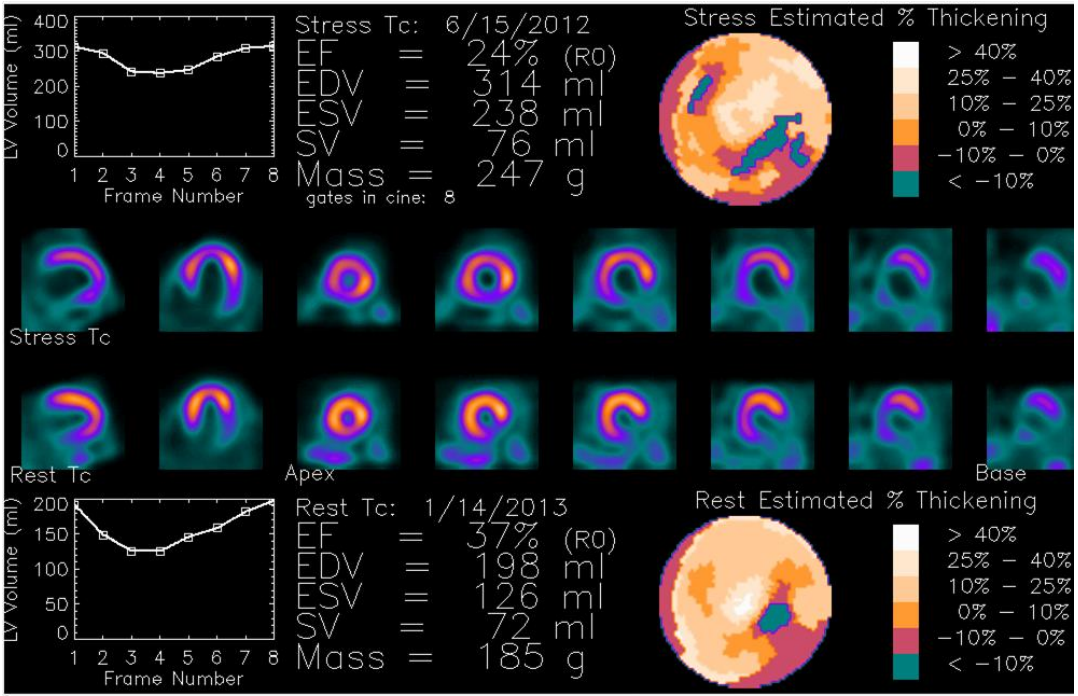


Patient Example 2: Pacing Away from Scar





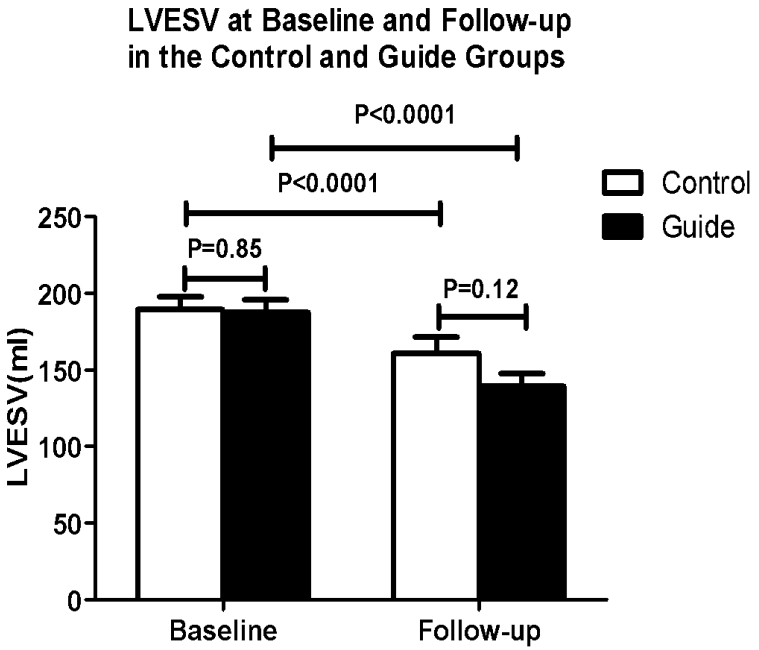
Patient Example 2: Outcome

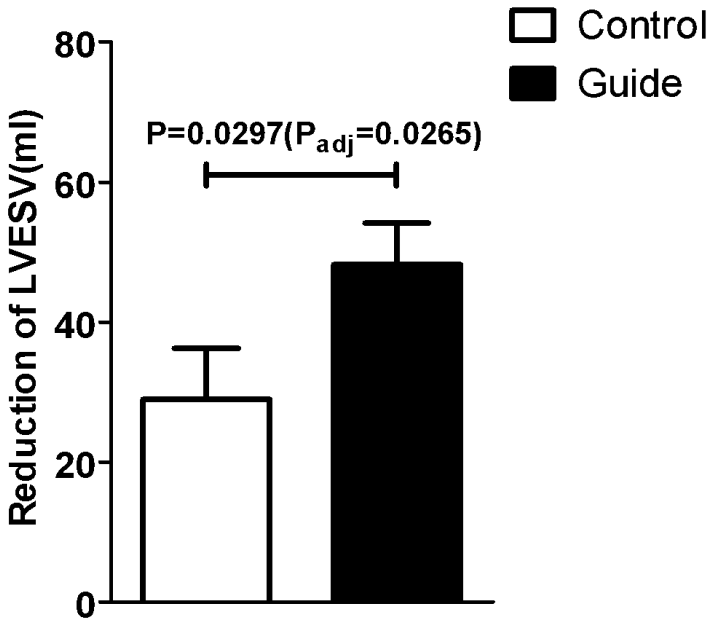


Baseline

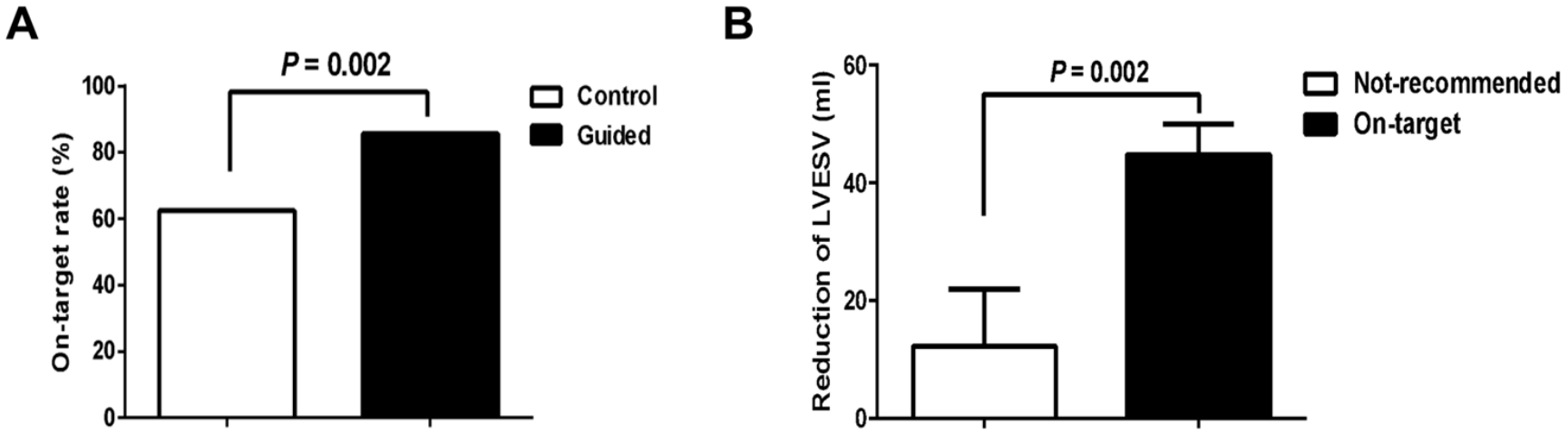
Follow-up

Results: Primary Endpoint

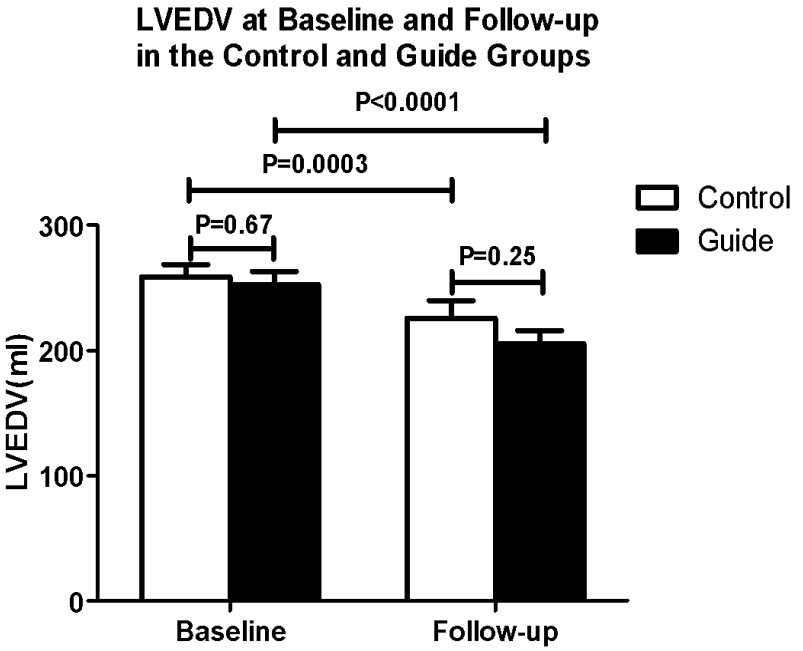


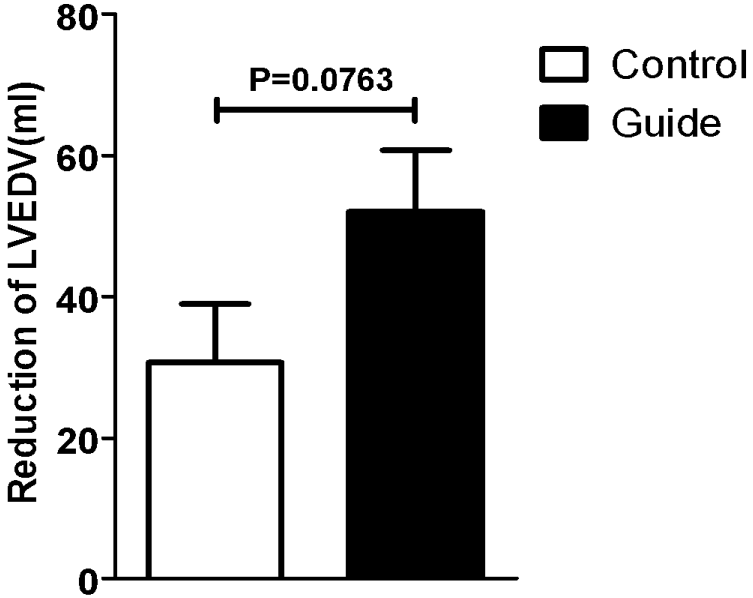


Results: Primary Endpoint by LV Lead Positions

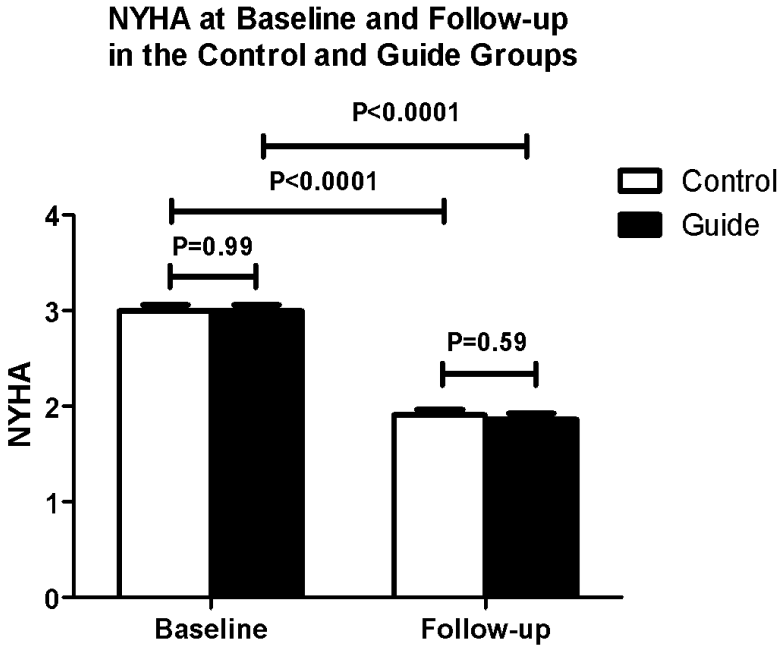


Results: Secondary Endpoint

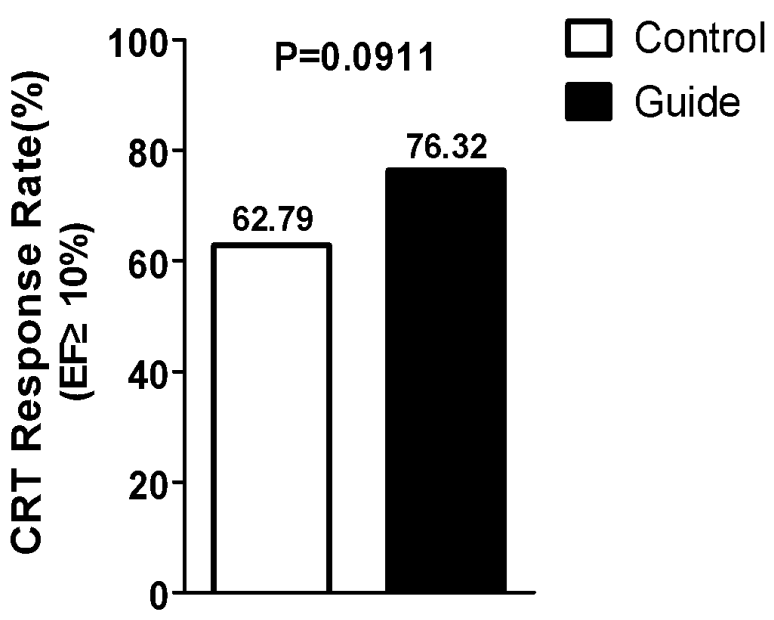


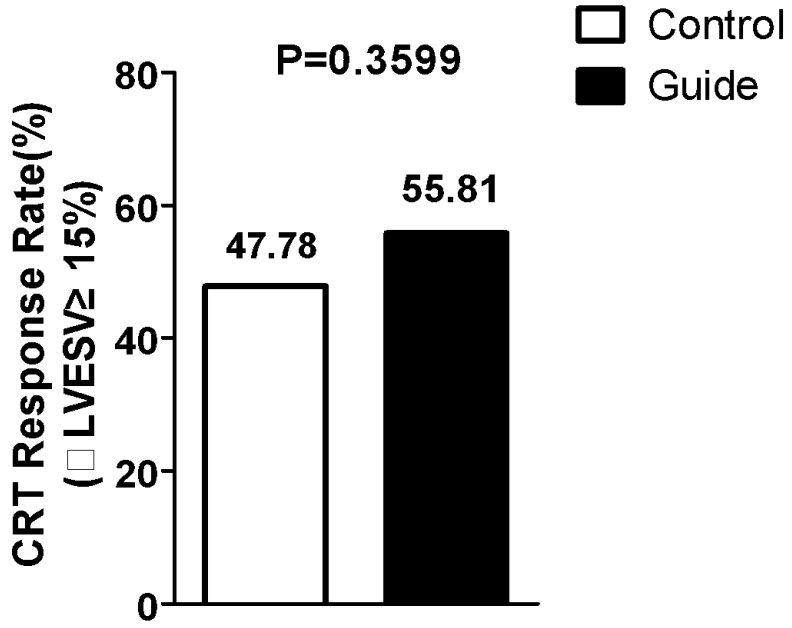


Results: Secondary Endpoint



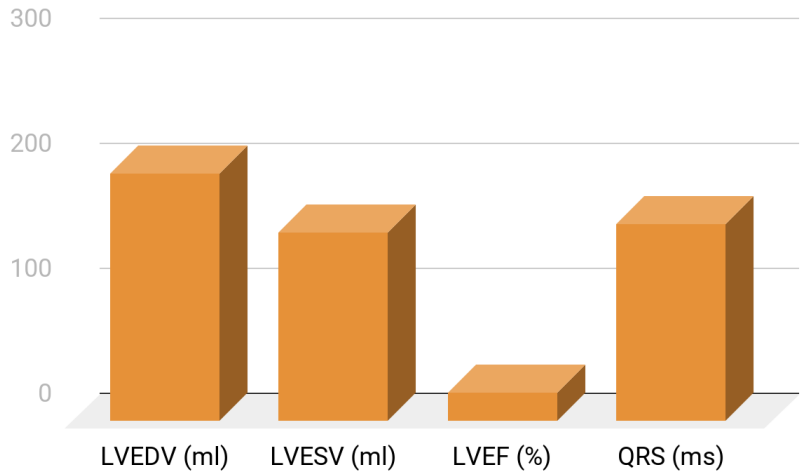
Results: Secondary Endpoint



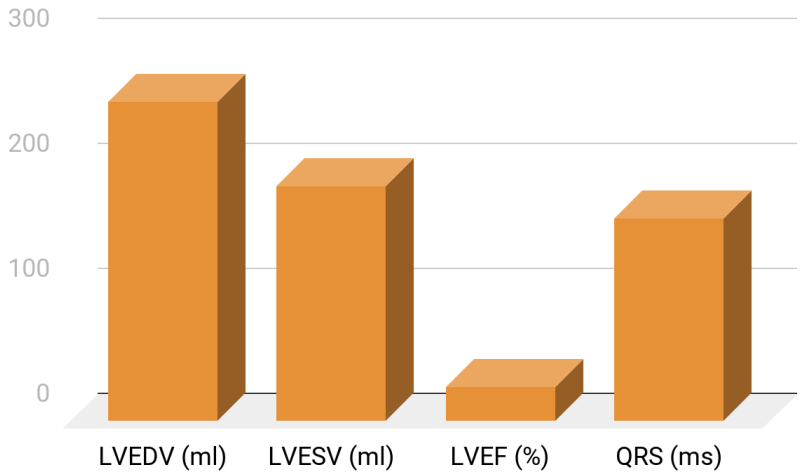


Discussion: Population and Response Criteria

TARGET (LVESV > 15%) [10]
70% vs. 55%

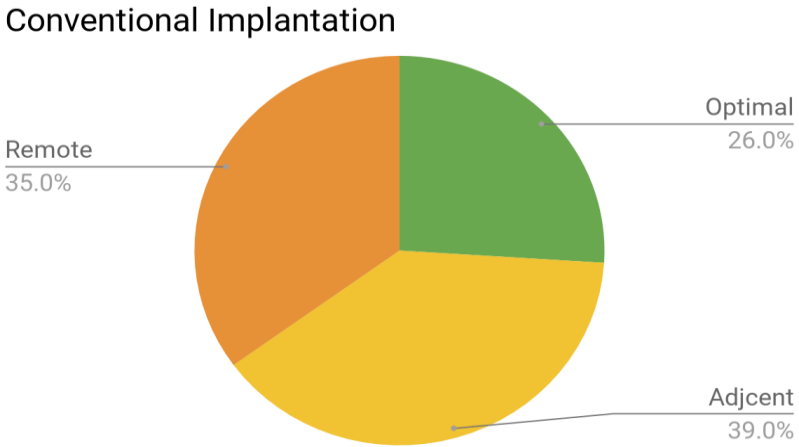


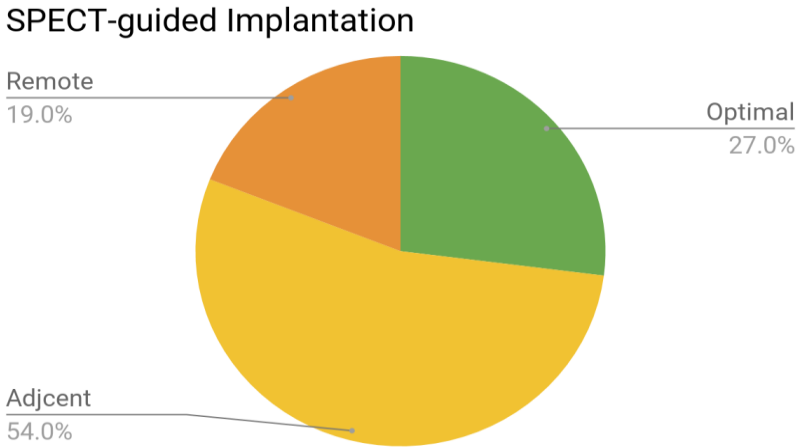
GUIDE-CRT (LVEF > 10%)
76% vs. 63%



GUIDE-CRT patients had significantly larger baseline LV volumes than TARGET patients, leading to similar response rates by different response criteria

Discussion: Guided Implantation





GUIDE-CRT used manual alignment between SPECT and fluoroscopy, resulting in suboptimal LV lead positions in a large portion of the patients

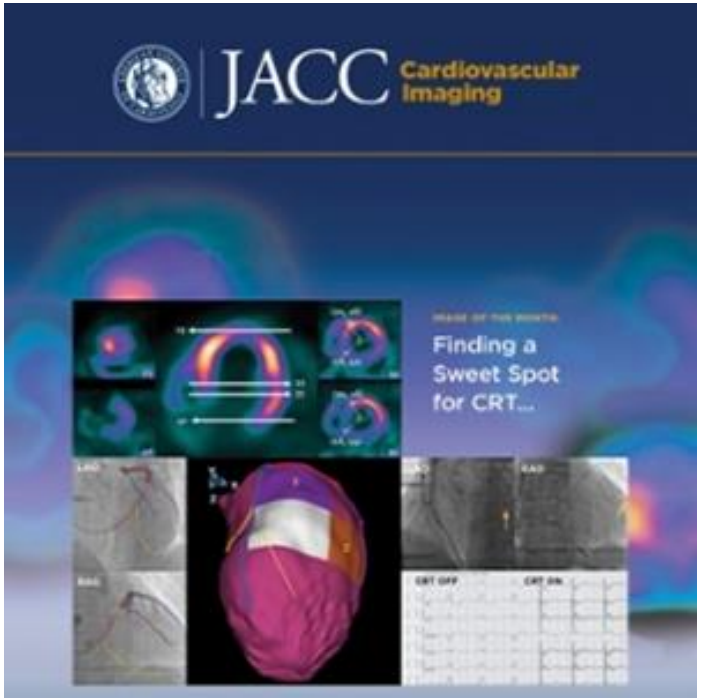
Conclusion

- Phase analysis of SPECT MPI, which integrated LV dyssynchrony, site of latest activation, and scar distribution, is a validated technique to optimize LV lead placement in the multicenter prospective setting.

- SPECT-guided LV lead placement can significantly improve CRT efficacy on LV reserve remodeling in chronic heart failure patients.

What's Next? 3D Fusion of SPECT and Fluoroscopy

The software is loaded on a laptop computer. Fluoroscopy venograms are manually transferred from the existing workstation.



What's Next? GUIDE-CRT II

- PI - Dr. Jiangang Zou, Nanjing Medical University
- 10 centers in China
- Randomized, controlled trial
- 300 patients with 6-month follow-up
- 3D fusion of SPECT and Fluoroscope to guide LV lead placement
- The first patient enrolled in March 2017

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Thank You!